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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/784,401

02/23/2004

Peter M. Bonutti

780-A04-002-1

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12/01/2006

PAUL D. BIANCO: FLEIT, KAIN, GIBBONS,
GUTMAN, BONGINI, & BIANCO P.L.
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

ANDERSEN, MICHAEL T

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/784,401 | Applicant(s) BONUTTI, PETER M. | |
| | Examiner M. Thomas Andersen | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election Requirement

Applicant's election with traverse of species III (Figures 9-15) in the reply filed on 9/25/2006 is acknowledged. The traversal is on the ground(s) that there is not a serious burden on the Examiner. This is not found persuasive because the different species require a different field of search. For example, species 1 contains a magnetic field generator separate from the suture insertion device while species 3 contains two magnetic elements making up jaws and a handle to actuate the magnetic elements. There is a great distinction between a magnetic field generator pulling a separate suture anchor through tissue and jaws used for suturing that happen to contain magnetic elements.

The requirement is still deemed proper and is therefore made FINAL. Accordingly, claims 1-11 and 19-31 are currently pending. Claims 12-18 are withdrawn.

Information Disclosure Statement

The information disclosure statements (IDS) received on 2/23/2004 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3734

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6-10, 19-20, 22, 24-29, and 31 are rejected under 35

U.S.C. 102(b) as being anticipated by Holmes, U.S. 5,417,701.

Holmes discloses a suturing instrument using magnets. Specifically, Holmes discloses, "With the needle in the desired position and orientation, the surgeon manipulates the instrument to insert the needle into, and part way through the tissue to be sutured. She then uses a second, similar instrument to grasp the needle and pull it the rest of the way through the tissue. This second instrument may include a magnet, which is preferably of lesser strength than the magnet in the first instrument. When this second instrument pulls the needle out of the tissue, the included magnet draws the needle into proper position within its jaws and holds the needle in this position until the needle is transferred to the first instrument."

Holmes discloses a permanent magnet on the 'first instrument' generating a magnetic field of sufficient strength to move the implement through the tissue. Moving the two magnetic elements, one on the first instrument and one on the second instrument, the magnetic field is varied to move the medical implement through the tissue. The magnet is positioned external to the tissue. The magnet is selectably positionable to move the medical implement through the tissue. The second instrument can be said to contain a magnetizable material; or, in the alternative, the needle can be said to comprise a magnetizable material.

Art Unit: 3734

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 11, 21, 23, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes, as applied to claims 1, 8, and 26 above, in view of Burns, U.S. 5,851,185.

Holmes does not disclose using an electromagnet. However, Burns discloses that it is well known in the art to use an electromagnet in the place of a permanent magnet. See, Burns col. 2, lines 53-56. It would have been obvious to one of ordinary skill in the art to use an electromagnet so as to better control the magnetic field when drawing the needle through tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

November 15, 2006

A handwritten signature in black ink, appearing to read "MJ Hayes", followed by a horizontal line.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER